FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)

Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Parkway, Gaithersburg, Maryland

AGENDA

October 21-22, 2010

Agenda: The committee will discuss considerations for the design of postmarketing studies for new drug application (NDA) 22-272 , OxyContin (oxycodone hydrochloride controlled-release) Tablets, Purdue Pharma, Inc. and NDA 22-321 Embeda (morphine sulfate extended-release with sequestered naltrexone hydrochloride) Capsules, Alpharma Pharmaceuticals, LLC and King Pharmaceuticals Research & Development, Inc., approved for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. The postmarketing studies are intended to be epidemiological or observational studies that will assess the known serious risks of these products and whether product-specific properties which are intended to deter misuse and abuse actually result in a decrease in the risks of misuse and abuse, and their consequences: addiction, overdose, and death.

Day 1- October 21, 2010

8:30 a.m.	Call to Order Introduction of Committee	**Jeffrey R. Kirsch, M.D.** Chair, ALSDAC
	Conflict of Interest Statement	**Kalyani Bhatt** Designated Federal Officer, ALSDAC
8:40 a.m.	Opening Remarks	Director, Division of Anesthesia and Analgesia Products CDER/FDA

Nature of the Problem of Prescription Opioid Misuse and Abuse

8:45 a.m.	Overview of the Risk of Abuse and Regulatory Discussions to Date to Reduce Abuse of Opioid Analgesics	Deputy Director for Safety, Division of Anesthesia and Analgesia Products CDER/FDA
9:05 a.m.	Premarketing Assessment of Abuse Deterrent Formulations	Pharmacologist, Controlled Substance Staff Office of the Center Director CDER/FDA

9:25 a.m.	Abuse of Marketed Opioid Analgesics and Their Contribution to the National Problem of Drug Abuse	(speaker) Division of Unintentional Injury Prevention National Center for Injury Prevention and Control Centers for Disease Control and Prevention
9:45 a.m.	Clarifying Questions	

Data Resources and Metrics Used to Assess Prescription Opioid Misuse and Abuse

9:55 a.m.	Societal Perspectives on the Assessment of Prescription Drug Abuse	(speaker) Professor, Department of Epidemiology College of Human Medicine Michigan State University
10:25 a.m.	BREAK	
10:40 a.m.	Substance Abuse and Mental Health Services Administration: Resources and Methods	Drug Abuse Warning Network (DAWN) Team Leader (acting) Center for Behavioral Health Statistics and Quality Substance Abuse and Mental Health Services Administration
11:00 a.m.	Available Data Resources to Assist in Measuring Abuse Behaviors, Patterns, and Outcomes	Epidemiologist, Division of Epidemiology Office of Surveillance and Epidemiology CDER/FDA
11:20 a.m.	Clarifying Questions	

Study Designs to Assess Prescription Drug Abuse

11:30 a.m.	Design Considerations in Epidemiological Studies of Abuse-Deterrent Opioids	Epidemiologist, Division of Epidemiology Office of Surveillance and Epidemiology CDER/FDA
11:50 a.m.	Statistical Considerations Regarding Studies Proposed by Industry Sponsors	Mathematical Statistician, Division of Biostatistics 7 Office of Biostatistics CDER/FDA
12:10 p.m.	LUNCH	

1:20 p.m. Clarifying Questions

Industry Presentations

1:40 p.m. Purdue Pharmaceuticals

3:10 p.m. BREAK

3:25 p.m. Clarifying Questions

4:00 p.m. Adjourn

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AGENDA *(Continued)*

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Day 2- October 22, 2010

8:30 a.m.	Call to Order Introduction of Committee	**Jeffrey R. Kirsch, M.D.** Chair, ALSDAC
	Conflict of Interest Statement	**Kalyani Bhatt** Designated Federal Officer, ALSDAC

Industry Presentation

8:40 a.m.	King Pharmaceuticals
10:10 a.m.	Clarifying Questions
10:30 a. m	BREAK
10:45 a.m.	Open Public Hearing
11:45 a.m.	LUNCH
12:45 p.m.	Committee Discussion
2:15 p.m.	BREAK
2:30 p.m.	Questions to the Committee
4:00 p.m.	Adjourn